



MAIL STOP RCE
Attorney Docket No. 28363U

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

TERAHARA et al.

Confirmation No.: 8337

Serial No.: 10/525,646

Group Art Unit: 1615

Filed: March 24, 2005

Examiner: SASAN, ARADHANA

For: **ADHESIVE PATCH CONTAINING PERGOLIDE**

DECLARATION OF KAZUNOSUKE AIDA

PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Kazunosuke Aida, declare as follows:

1. I am employed as a researcher at Tsukuba Laboratory of Hisamitsu Pharmaceutical Co., Inc. Tsukuba-shi, Ibaraki, Japan, and am engaged in pharmaceutical research. I have been in my current position since April 1, 1999. My responsibilities include study of patch formulations.

2. I received a Master's Degree in the field of pharmacy at Tokyo University of Pharmacy and Life Sciences, Tokyo, Japan.

3. I have reviewed the specification of United States Patent Application No. 10/525,646. I am an inventor of the subject matter claimed. I have reviewed the rejections to the pending claims set forth in the Official Action mailed from the United States Patent and Trademark Office on August 19, 2008. I have reviewed the references cited by the Examiner as the subject of rejections regarding the patentability of the claimed invention. Specifically, I have reviewed Miranda et al., U.S. Patent No. 5,656,286 (hereafter "Miranda"), and Hoffman, U.S. Patent No. 5,820,876 (hereafter "Hoffman".) In addition, I have prepared and/or overseen the preparation of and studied the various comparative patch compositions detailed herein. I have either conducted or overseen the patch property measurements of the same, and compared their adhesion properties and cohesion properties (Experimental data attached as Appendix A).

4. The specification of United States Patent Application No. 10/525,646, in Tables 1-4 at pages 34-37, demonstrate unexpectedly superior results achieved by the presently claimed patch formulations as compared to patch formulations lacking one or more of the copolymers recited in the presently pending claims. In particular, Examples 1-3 summarized in Table 1 and Examples 4-7 in Tables 3-4 show drug permeation rates per unit area of skin and adhesion and cohesion properties for compositions containing the presently claimed components. Comparative Examples 1-22 in Tables 1-4 show drug permeation rates for compositions lacking at least one of the components of the presently claimed formulation. *The data clearly shows superior skin permeation rates and patch properties, when compared to the drug permeation rates and patch properties for compositions lacking at least one of the claimed components.*

5. I hereby declare and state I have either conducted or overseen the work described here and in Appendix A. Comparative Example A was prepared, tested, and compared in Appendix A. A comparative patch example, Comparative Example A, was prepared using the same methods employed to prepare Example 1 as indicated in the present specification for U.S. Application No. 10/525,646 ("the present specification") except that the composition of the coating liquids was determined as listed in Table A (below). The skin permeability test and preparation property test for Comparative Example A were conducted in the same way as described for Example 1 in the present specification.

6. Comparative Example A was prepared to have a weight ratio (A:B) of 4:6 of the the styrene-isoprene-styrene block copolymer (A) to the 2-ethylhexyl acrylate – vinyl acetate copolymer (B). Comparative Example A's A:B ratio of 4:6 is outside the 1:1 to 9:1 range of A:B ratios recited in the present claims. See Appendix A. For comparison, Examples 1-3 and Comparative Example 1 are included below in Table A, and are the same measurements provided in the specification in Table 1 on page 34, and correspond to compositions recited in the present claims. Comparative Example 1 contains no 2-ethylhexyl acrylate – vinyl acetate copolymer (B). Examples 1, 2, and 3 have A:B ratios of 9:1, 7:3, and 5:5, respectively, which are within the range of A:B ratios recited in the present claims.

7. Comparative Example A with an A:B ratio of only 4:6 (outside the 1:1 to 9:1 range of A:B ratios recited in the present claims) exhibited a very poor Cohesion property. Comparative Example 1 with no 2-ethylhexyl acrylate – vinyl acetate copolymer (B) also

exhibited very poor Cohesion property. In contrast, the Applicants' claimed compositions, as exemplified by patch examples 1-3, having an A:B ratio of 1:1 to 9:1, exhibit unexpectedly superior Cohesion properties. Accordingly, the evidence overwhelmingly indicates that Applicants' claimed weight ratio (A:B) of 1:1 to 9:1 of the content of the styrene-isoprene-styrene block copolymer (A) to 2-ethylhexyl acrylate - vinyl acetate copolymer (B) is clearly distinguishable from compositions having A:B ratios outside the range claimed by the Applicants.

8. The evidence presented herein also indicates that one of skill in the art at the time of filing would not have had a reasonable expectation of successfully combining the teachings of Miranda et al. with the teachings of Hoffman et al. to devise the claimed patch having such unexpectedly superior results.

9. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Dec 19, 2008
Date

Kazunosuke Aida
Kazunosuke Aida

Appendix of Attachments:

Appendix A: Comparative Experimental Evidence (4 pages)